Zymed

Zymed Inc.
20 North Aviador Street
Camarillo, California 93010-8348
800.235.5941 - 805.987.9611
Fax 805.987.9532

September 3, 1999

Dockets Management Branch (HFA09305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Comments for Docket No. 99N092075

Comment 1

Reference: Section 1.1 An event has occurred

The term event is confusing because it generally refers to a device malfunction, serious injury, or death in the United States. Secondly, a device malfunction and inadequate design are not the same type of event. For example, an inadequate design parameter could cause a device malfunction, which may or may not be a reportable adverse event.

Comment 2

Reference: Section 3 User Error

The term user error needs to be clearly defined. User error is a very subjective term. Its interpretation will vary based on the reporter of the adverse event. Users and manufacturers tend to define what is a user error differently from one another.

Gretel Lumley
QA Engineer
Zymed
20 N. Aviador
Camarillo, CA 93010

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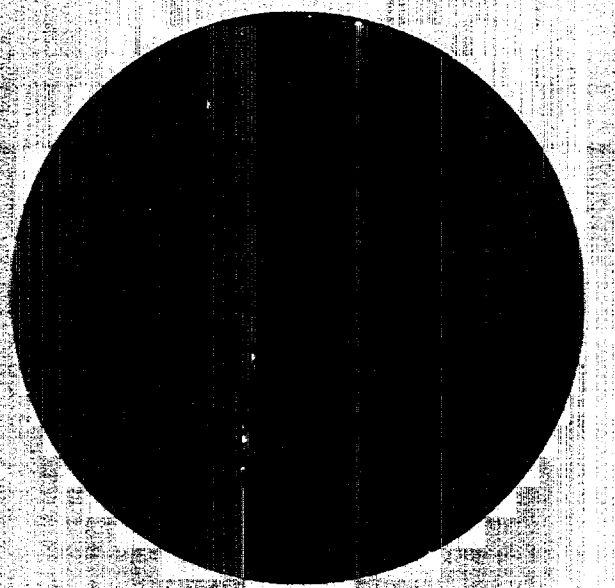

1 OF 1

ZYMED MEDICAL INSTRUMENTATION
(805) 987-9616
20 NORTH AVIADOR STREET
CAMARILLO CA 93010

SHIP TO:
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FOOD & DRUG ADMINISTRATION
RM.1061
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ROCKVILLE MD 20852

MD 2070-10

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